

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

July 13, 2020
Date of Report (date of earliest event reported)

OpGen, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation
or organization)

001-37367
(Commission
File Number)

06-1614015
(I.R.S. Employer
Identification Number)

708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(Address of principal executive offices)
(240) 813-1260
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OPGN	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On July 13, 2020, OpGen, Inc. issued a press release announcing its entry into a strategic partnership with Menarini Silicon Biosystems. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Document
99.1	Press Release issued by OpGen, Inc. dated July 13, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 14, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec

Title: Chief Financial Officer

Contact: Menarini Silicon Biosystems
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Menarini Silicon Biosystems Partners with OpGen to Broaden Distribution of CELLSEARCH Platform in North America

Strategic partnership will focus on commercializing CELLSEARCH platform for COVID-19 related use cases, along with other COVID-19 related products

Bologna, Italy, Huntingdon Valley, Pa, and Gaithersburg, Md., July 13, 2020 -- [OpGen, Inc.](#) (Nasdaq: OPGN), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, announced today that it has entered into a strategic co-promotion partnership with [Menarini Silicon Biosystems \(MSB\)](#), the pioneer of liquid biopsy and rare cell technologies, for its CELLSEARCH Circulating Endothelial Cell (CEC) Kit*, relevant to study progression of COVID-19 disease, and other COVID-19-related products.

Effective immediately, Menarini's CELLSEARCH system, CELLSEARCH CEC kit and COVID-19 related products will be marketed and sold by OpGen to infectious disease healthcare providers and researchers in North America through its dedicated team of sales and marketing experts.

The partnership will focus on promoting Menarini's CELLSEARCH system for CEC application, for the enrichment and enumeration of CEC from whole blood. CEC count is useful in studying the progression of COVID-19 and potentially in identifying patients at risk of developing more severe complications.

Both parties intend to expand the portfolio of COVID-19 products and platforms available over the coming months as they become available for sale. The OpGen commercial team will offer these products to its contacts in infectious disease hospitals, labs, research centers, along with distributors and other relevant stakeholders in the COVID-19 testing space.

“We are excited to partner with OpGen for the commercialization of our CELLSEARCH CEC Kit and our expanding portfolio of COVID-19 related products in the U.S. market,” said Fabio Piazzalunga, President and CEO of Menarini Silicon Biosystems, Inc. “This deal further extends the strategic distribution partnership which Menarini has built over the past 15 months in eleven European markets for OpGen’s subsidiary Curetis GmbH’s Unyvero platform and forms another element of our strategic presence in the infectious disease diagnostics market.”

“This commercial partnership further adds to the available portfolio of infectious disease tests that our OpGen sales and marketing team can bring to our network of customers in the U.S.,” stated Oliver Schacht, CEO of OpGen. “With Menarini already being our exclusive strategic distribution partner in Europe since early 2019, we see this as a natural extension and expansion of our partnership at a global level.”

“While MSB has traditionally focused on oncology molecular diagnostics we also have built a dedicated team of commercial experts in the U.S. in the infectious disease diagnostics market. Our team is excited to add several key products into their offering to bring a more complete solution to the COVID-19 pandemic situation,” Mr. Schacht added.

About Menarini Silicon Biosystems

Menarini Silicon Biosystems offers unique rare cell technologies and solutions that provide clinical researchers with access to unparalleled resolution in the study of cells and their molecular characterization. The company’s CELLSEARCH and DEPArray technologies together provide an end-to-end solution** for enumeration and sorting of rare cells with single-cell precision.

[Menarini Silicon Biosystems](#), based in Bologna, Italy, and Huntingdon Valley, Pa., U.S., is a wholly owned subsidiary of the Menarini Group, a multinational pharmaceutical, biotechnology and diagnostics company headquartered in Florence, Italy, with 17,640 employees in 136 countries.

About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with its subsidiaries, Curetis GmbH and Ares Genetics GmbH, OpGen is developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen’s product portfolio includes Unyvero, Acuitas AMR Gene Panel and Acuitas® Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

For more information, please visit www.opgen.com.

OpGen Forward-Looking Statement

This press release includes statements regarding the Menarini Silicon Biosystems commercial partnership for COVID-19 related tests by OpGen. These statements and other statements regarding the Companies’ future plans and goals constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product and services offerings, the rate of adoption of our products and services by hospitals and other healthcare providers, the realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the impact of COVID-19 on the Company’s operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. For a discussion of the most significant risks and uncertainties associated with OpGen’s business, please review the Company’s filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

* The Circulating Endothelial Cell Kit (CEC) is for Research Use Only. Not for use in diagnostic procedures. The performance characteristics, safety, and effectiveness have not been established and are not cleared or approved by the FDA.

**The workflow described is for research use only. Not for use in diagnostic procedures. The performance characteristics, safety, and effectiveness of the workflow have not been established and are not cleared or approved by the FDA.

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